

We Claim:

- 1 1. An extended release pharmaceutical composition comprising:
2 a blend of phenytoin sodium; and
3 one or more hydrophilic polymers; wherein the blend forms a matrix after
4 contacting an aqueous media and the matrix retains at least about 20% of the
5 phenytoin after 1 hour.
- 1 2. The composition according to claim 1, wherein the matrix retains at least about
2 30% of the phenytoin after 1 hour.
- 1 3. The composition according to claim 1, wherein the matrix retains at least about
2 60% of the phenytoin after 1 hour.
- 1 4. The composition according to claim 1, wherein the pharmaceutical
2 composition comprises a capsule containing the blend.
- 1 5. The composition according to claim 4, wherein the blend comprises a powder.
- 1 6. The composition according to claim 1, wherein the composition comprises
2 from about 40 percent to about 70 percent by weight of phenytoin sodium.
- 1 7. The composition according to claim 1, wherein the composition comprises
2 from about 10 percent to about 30 percent by weight of the one or more
3 hydrophilic polymers.
- 1 8. The composition according to claim 7, wherein the one or more hydrophilic
2 polymers comprise one or more of carbohydrate gum, cellulose ether, acrylic
3 acid polymer, and mixtures thereof.
- 1 9. The composition according to claim 8, wherein the carbohydrate gum
2 comprises one or more of xanthan gum, tragacanth gum, gum karaya, guar
3 gum, acacia, gellan gum, locust bean gum, and mixtures thereof.
- 1 10. The composition according to claim 9, wherein the carbohydrate gum
2 comprises xanthan gum.
- 1 11. The composition according to claim 10, wherein the cellulose ether comprises
2 one or more of methyl cellulose, hydroxypropyl cellulose, hydroxypropyl
3 methyl cellulose, hydroxyethyl cellulose, hydroxypropyl butyl cellulose,
4 carboxymethyl cellulose, and combinations thereof.

- 1 12. The composition according to claim 11, wherein the cellulose ether comprises
2 hydroxypropyl cellulose.
- 1 13. The composition according to claim 11, wherein the cellulose ether comprises
2 hydroxypropyl methylcellulose.
- 1 14. The composition according to claim 8, wherein the acrylic acid polymer
2 comprises carboxy vinyl polymer.
- 1 15. The composition according to claim 8, wherein the one or more hydrophilic
2 polymers comprise a combination of a cellulose ether and carbohydrate gum.
- 1 16. The composition according to claim 15, wherein the cellulose ether comprises
2 a combination of hydroxypropyl cellulose and hydroxypropyl methylcellulose
3 and the carbohydrate gum comprises xanthan gum.
- 1 17. The composition according to claim 1, further comprising one or more
2 pharmaceutically acceptable excipients.
- 1 18. The composition according to claim 17, wherein the one or more
2 pharmaceutically acceptable excipients comprise one or more of diluents,
3 lubricants and glidants.
- 1 19. The composition according to claim 18, wherein the diluents comprise one or
2 more of microcrystalline cellulose, powdered cellulose, lactose, starch,
3 mannitol, calcium hydrogen phosphate, and dextrose.
- 1 20. The composition according to claim 19, wherein the diluent comprises
2 microcrystalline cellulose.
- 1 21. The composition according to claim 18, wherein the lubricant comprises one or
2 more of talc, magnesium stearate, calcium stearate, stearic acid, hydrogenated
3 vegetable oil, polyethylene glycol, sodium stearyl fumarate and sodium
4 benzoate.
- 1 22. The composition according to claim 21, wherein the lubricant comprises
2 magnesium stearate.
- 1 23. The composition according to claim 21, wherein the lubricant comprises talc.
- 1 24. The composition according to claim 18, wherein the glidant comprises one or
2 more of colloidal silicon dioxide and talc.

- 1 25. The composition according to claim 24, wherein the glidant comprises
2 colloidal silicon dioxide.
- 1 26. The composition according to claim 1, wherein the composition has the
2 following in vitro dissolution profile when tested using USP Apparatus I in
3 water at 75 rpm:
- 4 a) not more than about 35 percent released in about 30 minutes,
5 b) between about 30 percent and about 75 percent released in about
6 60 minutes, and
7 c) not less than about 65 percent released in about 120 minutes.
- 1 27. A process for preparing an extended release pharmaceutical composition
2 comprising a blend of phenytoin sodium and one or more hydrophilic
3 polymers; the process comprising;
- 4 a) blending phenytoin sodium and one or more hydrophilic
5 polymers,
6 b) screening the blend, and
7 c) filling the blend into capsules.
- 1 28. The process according to claim 27, wherein the matrix retains at least about
2 30% of phenytoin after 1 hour.
- 1 29. The process according to claim 27, wherein the matrix retains at least about
2 60% of phenytoin after 1 hour.
- 1 30. The process according to claim 27, wherein the blend is filled into the capsule
2 in the form of a powder.
- 1 31. The process according to claim 27, wherein the composition comprises from
2 about 40 percent to about 70 percent by weight of phenytoin sodium.
- 1 32. The process according to claim 27, wherein the composition comprises from
2 about 10 percent to about 30 percent by weight of the one or more hydrophilic
3 polymers.

- 1 33. The process according to claim 27, wherein the one or more hydrophilic
2 polymers are selected from one or more of carbohydrate gum, cellulose ether,
3 acrylic acid polymer, and mixtures thereof.
- 1 34. The process according to claim 33, wherein the carbohydrate gum comprises
2 one or more of xanthan gum, tragacanth gum, gum karaya, guar gum, acacia,
3 gellan gum, locust bean gum, and mixtures thereof.
- 1 35. The process according to claim 34, wherein the carbohydrate gum comprises
2 xanthan gum.
- 1 36. The process according to claim 34, wherein the cellulose ether comprises one
2 or more of methyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl
3 cellulose, hydroxyethyl cellulose, hydroxypropyl butyl cellulose,
4 carboxymethyl cellulose, and combinations thereof.
- 1 37. The process according to claim 36, wherein the cellulose ether comprises
2 hydroxypropyl cellulose.
- 1 38. The process according to claim 36, wherein the cellulose ether comprises
2 hydroxypropyl methylcellulose.
- 1 39. The process according to claim 33, wherein the acrylic acid polymer comprises
2 carboxy vinyl polymer.
- 1 40. The process according to claim 33, wherein the one or more hydrophilic
2 polymers comprise a combination of a cellulose ether and carbohydrate gum.
- 1 41. The process according to claim 40, wherein the cellulose ether comprises a
2 combination of hydroxypropyl cellulose and hydroxypropyl methylcellulose
3 and the carbohydrate gum comprises xanthan gum.
- 1 42. The process according to claim 27, further comprising blending one or more
2 pharmaceutically acceptable excipients with the phenytoin sodium and one or
3 more hydrophilic polymers.
- 1 43. The process according to claim 42, wherein the pharmaceutically acceptable
2 excipients comprise one or more of diluents, lubricants, and glidants.

1 44. The process according to claim 27, wherein the composition has the following
2 in vitro dissolution profile when tested using USP Apparatus I in water at 75
3 rpm:

- 4 a) not more than about 35 percent released in about 30 minutes,
5 b) between about 30 and about 75 percent released in about 60
6 minutes
7 c) not less than about 65 percent released in about 120 minutes.

1 45. A method for controlling or treating one or more of generalized tonic-clonic
2 (grand mal) seizures and complex partial (psychomotor, temporal lobe)
3 seizures and prevention and treatment of seizures occurring during or following
4 neurosurgery in a patient in need thereof, the method comprising administering
5 an extended-release pharmaceutical composition comprising:
6 a blend of phenytoin sodium; and
7 one or more hydrophilic polymers; wherein the blend forms a matrix after
8 contacting an aqueous media and the matrix retains at least about 20% of the
9 phenytoin after 1 hour.

1 46. The method according to claim 45, further comprising administering an
2 additional pharmaceutically active agent.

1 47. The method according to claim 46, wherein the additional pharmaceutically
2 active agent comprises one or both of phenobarbitone and pentobarbital.

1 48. The method according to claim 45, wherein the one or more hydrophilic
2 polymers comprise one or more of carbohydrate gum, cellulose ether, acrylic
3 acid polymer, and mixtures thereof.